REMARKS

The claims have been amended in a manner that is believed to distinctly and clearly claim the subject matter that is regarded as applicants' invention. Claim 11 has been canceled.

Objection Under 37 CFR 1.75(c)

Claim 7 is objected to for failing to further limit a previous claim. In response, Claim 7 has been canceled.

Claim Rejections –35 USC §112

Claims 1-2 and 4-11 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants view as their invention. The Examiner raises several objections that are addressed below. What seems to have not been appreciated is that, depending on the type of test performed, it may be desirable to conduct follow-on test for additional diagnostic information over different lengths of time. For example, a drug-of-abuse analysis is positive or negative and so a second aliquot of sample would be retained for only a short period of time, possibly to confirm test accuracy. On the other hand, if a standard metabolite panel of tests is conducted, the diagnosis of a possible disease may require several days and additional testing may be needed to confirm such diagnosis. In both cases, the initial test is done on the first aliquot, and the follow-on test is done on the second aliquot that has been in storage on the analyzer "without requiring that a second patient sample be obtained" (last lines of [0042]). In general, the time required to perform a specific test is usually determined by the nature of the test itself. In the present invention, the identity of a specific test determines how long a second aliquot is to be stored on an analyzer; this is not related to the length of time to perform the specific test itself.

The Examiner's specific questions involve:

Examiner's Question	Clarification
It is not apparent how the storage time is related to the test being performed. (Claims 1 and 8 and 9)	See [0042] and [0043]. A look-up table correlates the length of storage to the likelihood of follow-up or additional testing that may be desirable as part of a full diagnosis. The initial test is done on the first aliquot, and the follow-on test is done on the second aliquot that has been in storage.
It is not apparent where the first aliquot is deposited after extraction. Is it retained in the extraction means? Are there different extraction means?	See [0041] and preamble of claim 1. The first sample aliquot is dispensed into a cuvette and tested (lines 4-5) in the same manner as is the second sample aliquot (last 7 lines of the paragraph).
Tests on the second aliquot are performed after tests on the first are completed (preamble), but are claimed to be performed during the storage time.	See [0041]. Additional tests are performed on the second aliquot portion after tests on the first are completed. Follow-on tests may be conducted on the second aliquot, depending on the test results from the first aliquot. The second aliquot is stored for the predetermined period of time to make this possible. See [0042], lines 5-8;
The relation between the identity of tests performed on the first aliquot and the storage time of the second aliquot is unclear. (Claim 8)	See [0042] and [0043]. A look-up table correlates the length of storage to the likelihood of follow-up or additional testing that may be desirable as part of a full diagnosis. The initial test is done on the first aliquot, and the follow-on test is done on the second aliquot that has been in storage.
"Is it supposed to mean that there are specific tests associated with each of the different multiple analytes, which define the time for performing the test?"	The time required to perform a specific test is usually determined by the nature of the test itself. In the present invention, the identity of a specific test determines how long a second aliquot is stored on an analyzer; this is not related to the length of time to perform the specific test itself.

Claim 1 specifies a first embodiment of the invention wherein a period of time is identified in bar code indicia during which the second aliquot portion is stored within the analyzer.

Claim 8 specifies another embodiment of the invention wherein the bar code indicia identifies the tests to be performed upon a patient's specimen and the tests to be performed determine the period of time the second aliquot portion is to be retained in storage. A look-up table may be used to correlate how long the second aliquot of specimen is to be stored based on the identity of tests to be performed.

In view of the amendments and the discussion provided above, it is respectfully requested that the rejection of claims 1-2 and 4-11 under 35 USC §112, second paragraph, be withdrawn.

Claim Rejections –35 USC §102

Claims 1-3, 5 and 7-9 and 11 are rejected under 35 USC §102(a) as being anticipated by Young (US 3,565,582). The Examiner cites Young for teaching "methods and means for handling blood test specimens" wherein:

> "some of the serum is transferred from the initial or first vessel to the other or second vessel. A sample of the specimen is withdrawn and is subjected to the test sequence which includes the testing and presentation of the test result. These steps, withdrawal of the sample, testing and presentation of test results are accomplished according to a predefined time schedule. An added step in the process, and one which may be accomplished at any point in the process this far described, is to apply to the container indicia or data which will identify the specimen and the test to which it is to be subjected" (col. 3, lines 60-72). *"Upon withdrawal of a test sample a specimen upon which other tests are to be run is placed in storage and is then submitted to another timed sequence of steps including sample withdrawal, testing and presentation of test results. The storage step may be included in the time sequence of the steps. The step of reading the data in the container and correlating that data with test results will also be included* in *the timed sequence of steps"* (col. 4, lines 10-16).

What Young discloses in this section is no more than storing an original specimen on board an analyzer for possible subsequent processing as well as the use of indicia on the original sample container to identify tests to be conducted on the sample. In contrast, Claim 1 requires "providing bar code indicia on the original sample container to indicate a predetermined period of storage time" and claim 8 requires "using the identity of said tests to determine a storage period of time for said second aliquot portion". Young does not do either of these; Young discloses "*a specimen upon which other tests are to be run is placed in storage*" and is totally silent as to how long a sample is to be stored and how this might be related to the tests to be performed.

The Examiner further cites Young for disclosing:

> "a double vessel container for blood and its serum, which is capable of bearing data identifying the blood and the test prescribed together with apparatus for reading that data and for conducting tests according to a predetermined relative time schedule" (col. 3, lines 48-53).

Here again, Young discloses no more than the use of indicia to identify tests to be conducted on a specimen (it is the testing apparatus that conducts tests according to a predetermined relative time schedule) and is totally silent as to how long a sample is to be stored and how this might be related to the tests to be performed..

The Examiner also cites Young for disclosing:

> "It is implicit in the preceding discussion that the several steps in the method may be separated by storage steps in which specimens are stored in the double vessel container. Any storage prior to application of identification data to the container must be controlled to prevent loss of identity. In addition, in the interval between removal of the sample and correlation of identification data and test result there must be a control to enable proper correlation which involves accomplishment of any storage steps on a timed basis for integral multiples of the unit time period employed in the process" (col. 8, lines 10-20) (which depends on the test to be performed, see col. 7).
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> "A cover 44 is provided for the container to insure cleanliness prior to use and to insure that the blood and serum are not contaminated with dirt and other foreign matter once they are placed in the container" (col. 6, lines 19-22).

Here Young only discloses that specimens are stored on the apparatus in a single container **10** having concentric vessel portions **12** and **18**, whole blood being retained in

inner vessel portion **12** and serum in outer vessel portion **18** (Col 5, lines 30-32). Young again is totally silent as to how long a sample is to be stored and how this might be related to the tests to be performed.

The Examiner then states a belief "that the disclosure in terms, which were conventional for the state of the prior art in the time of Young's invention, covers the subject matter of the indicated claims."

Applicants note that the disclosures cited above teach only that an original specimen container be stored on board an analyzer for possible later testing. Young does not teach:

- providing bar code indicia on an original sample container to indicate a predetermined period of storage time and storing a second aliquot portion of the original sample within said analyzer for said predetermined period of storage time (Claim 1); or,
- providing bar code indicia on an original sample container to indicate tests to be completed on the patient's sample, and then using the identity of said tests to determine a storage period of time for a second aliquot portion of the original sample (Claim 8).

Since these limiting process steps are not disclosed by Young, an anticipation rejection under 35 USC §102(a) that requires disclosure of each and every feature of the claimed invention cannot be sustained. Applicants thus respectfully request that the rejection of claims 1 and 8 under 35 USC §102(a) be withdrawn.

With regard to the rejection of claims 2,4-6 and 9-10 under 35 USC §102(a), since claim 1 patentably distinguishes over Young and is allowable, claims 2, 4-6 and 9-10 are at least allowable therewith because they depend from an allowable claim. Consequently, the Examiner is requested to withdraw the rejection of claims 2, 4-6 and 9-10 under 35 USC §102(a).

Claim Rejections –35 USC §103

Claims 4, 6 and 10 are rejected under 35 USC 103(a) as being unpatentable over Young. Since claim 1 patentably distinguishes over Young and is allowable, claims 4, 6 and 10 are at least allowable therewith because they depend from an allowable claim. Consequently, the Examiner is requested to withdraw the rejection of claims 2, 6 and 10 under 35 USC §103(a).

Claims 1-2, 4, and 6-11 are rejected under 35 USC 103(a) as being unpatentable over Mazza (US 5,350,564) in view of Thorne et al (US 4,678,752, IDS). The Examiner cites Mazza for disclosing:

> 1) A conveyor system for feeding individual sample tubes . . . either from groups or batches . . . identifying the individual sample tubes and conveying and/or temporarily storing the individual sample tubes as required . . . while test results are obtained, and returning the tubes to groups in response to an indication that analysis of a particular sample is complete and verified as reliable.
>
> 2) This storage and dwell time feature makes possible the recall to an analyzer module of any particular sample in the event the results of a test are not verified as reliable. This latter feature is of high importance with stat samples. If the test results for any stat sample are not reliable, the sample will be recalled to the analyzer and retested. Only when the test results of each sample are verified will the sample be delivered to the off-loading area.

Mazza does no more than teach temporarily storing a sample until such time as valid test results are reported at which point in time, the sample are off-loaded from the analyzer. In contrast, Applicants' store a sample aliquot for a period of time that is identified by indicia on the original sample container irrespective of whether the previously reported test results are valid. Claim 1 specifies:

- providing bar code indicia on the original sample container to indicate a predetermined period of storage time; and,
- storing an aliquot vessel containing a second aliquot portion within the analyzer for said predetermined period of storage time

As examples, attention is turned to paragraph [0041], wherein two weeks is cited as an exemplary amount of storage time and to paragraph [0044] wherein one to two days is cited as an exemplary amount of storage time.

Since Mazza only teaches storing a sample until such time as valid test results are reported, a time that may be as short as one hour, Mazza cannot make obvious Applicant's invention wherein a sample is stored for a period of time (for example one or two days or one to two weeks) that is identified by indicia on the original sample container after the requisite tests are completed.

The Examiner thus turns to Thorne's disclosure of providing an expiration date for reagents in a bar code and suggests that it would have been obvious to modify Mazza's method "to discard the samples which were retained in the storage compartment for the period of time exceeding the expiration date (the time period) and to alert the user about the expiration of the time period."

Applicants recognize that the Supreme Court's opinion in the recent case *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 550 U. S. ___ (Apr. 30, 2007) concedes that "invention in most, if not all instances, rely upon building blocks long since uncovered, and claimed discoveries almost of necessity, will be combinations of what, in some sense, is already known" (*KSR*, slip op at 15). For this reason, the KSR rulings maintain that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art . . . and that it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." (*KSR*, slip op. at 14 bridging to 15, underlining added for emphasis)

In rejecting claims 1-4, 6 and 9-10 of the present application under 35 USC 103(a) as being unpatentable over Mazza in view of Thorne, the Examiner has suggested that the reason an artesian would combine the teachings of Mazza and Thorne is to avoid re-testing a sample that may be "degrading in time". Such a reason does not apply to the instant invention wherein samples are stored in "temperatures between minus 4 degrees Centigrade and plus 20 degrees Centigrade and relative humidity between about 5% and 75%", like maintained in storage compartment 50 (see

paragraph **[0037]**) and under these condition, samples do not degrade over periods of time like one to two weeks.

KSR further requires that "a court must ask if the improvement is more than the predictable use of prior-art elements according to their established functions." (*KSR*, slip op. at 4, underlining added for emphasis). In making the present rejection, the Examiner has added bar code information relating to the expiration date of a solution (a reagent, or in the instant invention, a patient's specimen) to a stored solution so as to enable an operator to "discard samples which were retained in the storage compartment for a period of time exceeding the expiration time or date." There is no reason to add information relative to the "expiration date of a sample" to an original sample container to indicate a predetermined period of storage time after tests on said first sample aliquot are completed, reported, or analyzed by a physician to allow for re-testing of the patient's specimen (Claim 1), or wherein bar code indicia are provided on the original sample container to indicate the tests to be completed on the patient's sample and using the identity of those tests to determine a storage period of time for a second aliquot portion (Claim 8).

For the above reasons, Applicants respectfully submit that the rejection of claims 1-4, 6 and 9-10 as being unpatentable under 35 USC 103(a) over Mazza and Thorne is believed to be overcome and is requested to be withdrawn.

Claim 5 is rejected under 35 USC 103(a) as being unpatentable over Mazza in view of Thorne et al and further in view of art, for example Boosalis et al (US 4,362,698, IDS). In response, since claim 1 patentably distinguishes over Young and is allowable, claim 5 is at least allowable therewith because it depends from an allowable claim. Consequently, the Examiner is requested to withdraw the rejection of claim 5 under 35 USC 103 For these reasons, the Examiner's rejection of claim 5 as being unpatentable is believed to be overcome and is requested to be withdrawn.

Conclusion

Applicants believe that this application contains patentable subject matter and that the foregoing amendments provide a basis for favorable consideration and

allowance of all claims; such allowance is respectfully requested. If any matter needs to be resolved before allowance, the Examiner is encouraged to call Applicants' representative at the number provided below.

Respectfully submitted,

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